



Food and Drug Administration
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March 26, 2015

Covidien, LLC
Megan Fessenden
Senior Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K142865
Trade/Device Name: Nellcor Bedside SpO₂ Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 24, 2015
Received: February 27, 2015

Dear Ms. Fessenden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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Enclosure

Nellcor Bedside SpO₂ Patient Monitoring System
Indications for Use Statement

510(k) Number, if known: K142865

Device Name: Nellcor Bedside SpO₂ Patient Monitoring System

Indications for Use:

The Nellcor Bedside SpO₂ Patient Monitoring System is indicated for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The Nellcor Bedside SpO₂ Patient Monitoring System is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra hospital transport, or home environments.

Note:

- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.
- Home environment includes any environment other than a professional healthcare facility or clinical laboratory where a device may be used.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nellcor Bedside SpO₂ Patient Monitoring System
510(k) Summary

Submitter

Address	Covidien LLC 6135 Gunbarrel Ave Boulder, CO 80301
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Company Contact	Megan Fessenden, Sr. Regulatory Affairs Specialist
Date Prepared	February 23, 2015

Device

Trade Name	Nellcor Bedside SpO ₂ Patient Monitoring System
Common Name	Pulse Oximeter
Classification Name	Oximeter (21 CFR 870.2700)
Classification	Class II
Product Code	DQA
Branch	Anesthesiology

Device Description

The Nellcor Bedside SpO₂ Patient Monitoring System is a pulse oximeter designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The Nellcor Bedside SpO₂ Patient Monitoring System is intended to be used with one of a range of Nellcor OxiMax oxygen transducers (sensors). The subject device displays digital values of SpO₂ and pulse rate. Pulse amplitude is displayed by means of a 'blip bar' presentation or plethysmographic waveform. The Nellcor Bedside SpO₂ Patient Monitoring System can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (from 80V AC to 264V AC) or alternately by an integral sealed 7.2V, 83W/hr rechargeable lithium-ion battery.

The intended patient population includes neonatal, pediatric, and adult patients during both motion and no motion conditions. The patient may be well or poorly perfused and undergoing monitoring in hospitals, hospital-type facilities, intra-hospital transport, or home environments.

Intended Use

The Nellcor Bedside SpO₂ Patient Monitoring System is indicated for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The Nellcor Bedside SpO₂ Patient Monitoring System is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused and undergoing monitoring in hospitals, hospital-type facilities, intra hospital transport, or home environments.

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Note:

- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
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- Home environment includes any environment other than a professional healthcare facility or clinical laboratory where a device may be used.

Technological Characteristics

The subject and predicate devices measure functional oxygen saturation non-invasively via a light signal interacting with tissue, by utilizing the time-varying changes in tissue optical properties that occur with pulsatile blood flow.

At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Pulse Oximetry – Used to non-invasively measure functional oxygen saturation
- Regulation Number – 870.2700 Oximeter
- Product Code - DQA
- Collect signal via light signal interacting with tissue – red & infrared light emitting diodes (LEDs) are used as light sources and a photodetector senses the signal strengths of the two wavelengths of light.
- Use of software including the same oximetry algorithm to processes the information – providing real-time values of SpO₂, pulse rate, and pulse amplitude.
- Use of an alarm management system – SatSeconds allows the caregiver to set the limits on desaturation and pulse rate including specifying acceptable duration and magnitude.
- Use of commonly used materials
- Limited contact with skin, no contact with mucous membranes or non-intact skin – designed cleaning and low-level disinfecting for multiple uses
- Are electrically operated – come equipped with an internal battery supply and an external power cord
- Operating and Storage Temperature and Humidity
- Availability of Nurse Call connectivity
- Compliance to Electrical Safety and EMC standards
- Intended patient population and sensor compatibility
- SpO₂ and Pulse rate accuracy specifications

The following technological differences exist between the subject and predicate devices:

NOTE: When the difference does not apply to all predicates, the applicable predicate(s) are noted in parentheses.

- Updated compliance to current standards
- Homecare use environment (Nellcor Bedside SpO₂ Patient Monitoring System (Libra) and Nellcor Bedside Respiratory Patient Monitoring System only)

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- Physical Dimensions and/or weight (All)
- Operating Altitude (N-600x and Nellcor Bedside Respiratory Patient Monitoring System only)
- Storage Altitude (Nellcor Bedside Respiratory Patient Monitoring System only)
- Display size (N-600x and Nellcor Bedside Respiratory Patient Monitoring System only)
- Printed Circuit Board Assembly (PCBA) (N-600x and Nellcor Bedside SpO₂ Patient Monitoring System only)
- Ability to measure respiratory rate is only available on Nellcor Bedside Respiratory Patient Monitoring System

Substantial Equivalence

The Nellcor Bedside SpO₂ Patient Monitoring System is considered to be substantially equivalent to the devices presented in **Table 6-2**.

Table 6-2 – Substantial Equivalence

Device Manufacturer	Device Name	510(k) Number	Date of Clearance
Covidien LLC	Nellcor OxiMAX N-600x Pulse Oximetry System	K123581	May 9, 2013
Covidien LLC	Nellcor Bedside SpO ₂ Patient Monitoring System	K120773	July 12, 2012
Covidien LLC	Nellcor Bedside Respiratory Patient Monitoring System	K130320	February 4, 2014

Performance Testing - Bench

Bench testing was conducted on the Nellcor Bedside SpO₂ Patient Monitoring System to ensure the subject oximeter met design specifications. The device was tested to medical electrical equipment standards, environmental testing standards, medical device software standards, and usability engineering standards. These standards include:

Standard	Title
ISO 9919	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use
ISO 80601-2-61	Medical Electrical Equipment – Part 2-61: Particular Requirements for the Basic Safety and Performance of Pulse Oximeter Equipment
IEC 60601-1: 3 rd Edition	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
IEC 60601-1-8	Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in medical Electrical Equipment and Medical Electrical Systems
IEC 60601-1-11	Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment
IEC 60068-2-1	Environmental Testing – Part 2-1: Tests – Test A: Cold
IEC 60068-2-2	Environmental Testing – Part 2-2: Tests – Test B: Dry Heat

Nellcor Bedside SpO₂ Patient Monitoring System
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Standard	Title
IEC 60068-2-6	Environmental Testing – Part 2-6: Tests – Fc: Vibration (sinusoidal)
IEC 60068-2-13	Basic Environmental Testing Procedures – Part 2: Tests – Test M: Low Air Pressure
IEC 60068-2-27	Environmental Testing – Part 2-27: Tests Test Ea and Guidance: Shock
IEC 60068-2-30	Environmental Testing – Part 2-30: Tests – Test Db: Damp Heat, Cyclic
IEC 60068-2-64	Environmental Testing – Part 2-64: Tests – Test Fh: Vibration, Broadband Random and Guidance
IEC 62304	Medical Device Software – Software Lifecycle Processes
IEC 62366	Medical Devices – Application of Usability Engineering to Medical Devices

The results of this testing show that the subject device meets the product requirements and specifications including: SpO₂ accuracy without motion of $\pm 2\%$ from 70-100%, SpO₂ accuracy with motion of $\pm 3\%$ from 70-100%, and pulse rate of $\pm 3\%$ from 20 to 250 BPM, and is substantially equivalent to the identified predicate devices.

Performance Testing – Clinical

There was no new clinical testing conducted on the subject Nellcor Bedside SpO₂ Patient Monitoring System. Clinical testing was conducted on a similar Nellcor pulse oximetry device utilizing the same PCBA module to demonstrate the accuracy of the oximetry performance during both motion and no motion conditions.

Summary

The Nellcor Bedside SpO₂ Patient Monitoring System is a pulse oximeter that is substantially equivalent to the identified predicate pulse oximeters.